

EPA REGISTRATION NUMBER 70310-6 Vol. 2

PROCESSING REQUEST

Reg # 70310-6

Decision # 526296

Description: adding producer to CSF (ALT.)

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 3/10/17

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: ALT. 1/30/17

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: C. Kendrick

Division: BPPD

Phone: 703 347 0168

Date: 3/15/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 10, 2017

Shyam K. Chari
President
Agro Logistics Systems, Inc.
PO Box 5799
Diamond Bar, CA 91765

Subject: Non-PRIA (Pesticide Registration Improvement Act) Formulation Amendment –
Adding producer to CSF
Product Name: Debug AZA MUP
EPA Registration Number: 70310-6
Application Date: 2/13/2017
OPP Decision Number: 526296

Dear Mr. Chari:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 03/06/2015
- Alternate CSF #1 dated 01/30/2017

Any CSFs other than those listed above are superseded/no longer valid.

Page 2 of 2
EPA Reg. No. 70310-6
OPP Decision No. 526296

If you have any questions, please contact Cody Kendrick by phone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

A handwritten signature in black ink, reading "Andrew C. Bryceland". The signature is written in a cursive style with a large, stylized "A" and "B".

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

S: 999100

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☐ Yes ☒ No

Tracking

Company: 70310 AGRO LOGISTIC SYSTEMS, INC.

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-6 Product Name: DEBUG AZA MUP

Override#:

Me Too
Section3:Me Too Product
Name:

Application Date: 13-Feb-2017



OPP Rec'd Date: 15-Feb-2017



Front End Date: 16-Feb-2017



Risk Manager Send Date: 16-Feb-2017



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

CSF AMENDMENT

Receipt Content

Des

CSF

III

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 16, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. SHYAM K. CHARI
AGRO LOGISTIC SYSTEMS, INC.
PO Box 5799
DIAMOND BAR, CA 91765

PRODUCT NAME: DEBUG AZA MUP
COMPANY NAME: AGRO LOGISTIC SYSTEMS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 70310-6
EPA RECEIPT DATE: 02/15/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service

{999100u~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S- 999100

EPA File Symbol/Reg. No.

70310-6

Pin-Punch Date:

2/15/2017

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Bayceland

Date: 2-16-17

Remarks:

S: 999100

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Company: 70310 AGRO LOGISTIC SYSTEMS, INC.

Billable: ☒ Yes ☐ No

Tracking

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-6

Product Name: DEBUG AZA MUP

Override#:

Me Too
Section3:

Me Too Product
Name:

Application Date: 13-Feb-2017

OPP Rec'd Date: 15-Feb-2017

Front End Date: 16-Feb-2017

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:

New Ingredient:

Receipt Description:

CSF AMENDMENT

Receipt Content

CSF

View/Edit

Form A:

Signature Date:

Form B:

Signature Date:



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70310-6	2. EPA Product Manager ANDREW BRYCELAND	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DEBUGAZA MVP	PM#	
5. Name and Address of Applicant (Include ZIP Code) AGRU LOGISTIC SYSTEMS, Inc. PO BOX 5799, DIAMOND BAR, CA 91765 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

ADD NAME AND ADDRESS OF ADDITIONAL PRODUCER (CSF #2)
AS AN ATTACHMENT TO CSF (ALTERNATE)
ADD NEW EPA ESTABLISHMENT NUMBER TO THE MASTER LABEL

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name SITYAM K. CHARI	Title PRESIDENT	Telephone No. (Include Area Code) 714-990-9220	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)
2. Signature 	3. Title PRESIDENT		
4. Typed Name SITYAM K. CHARI	5. Date 02-13-2017		

TRANSMITTAL DOCUMENT**NAME AND ADDRESS OF SUBMITTER:**

Agro Logistic Systems, Inc.
P.O. Box 5799
Diamond Bar, CA 91765

COMPANY OFFICIAL:

Shyam Chari
President
Agro Logistic Systems, Inc.
Tel: (714) 990-9220; Email: shyam@agrologistic.com

REGULATORY ACTION:

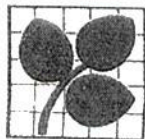
NON-PRIA Debug-AZA MUP Alternate Formulation (EPA File Symbol 70310-6)

TRANSMITTAL DATE:

February 13, 2017

LIST OF SUBMITTED DOCUMENTS/STUDIES:

No. of Copies	MRID #	EPA STUDY TITLE	OCSPP GUIDELINES
VOLUME 1 OF 1			
1	XXXXXX-01	Transmittal Document	
VOLUME 2 OF 2			
1	XXXXXX-02	EPA Form 8570-1	
2	XXXXXX-03	CSF Alternate	
2	XXXXXX-04	Master Label	



**AGRO
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.

Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

February 13, 2017

Cody Kendrick,
Regulatory Action Leader,
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs,
United States Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Reference: Debug Aza MUP- EPA Registration Number 70310-6
Debug TGAI- EPA Registration Number 70310-4

Dear Mr. Kendrick:

Please refer to our various email conversations and your response.

Please find attached the Non- PRIA amendments for the above products.

For all products we are attaching the Transmittal Forms, EPA Form 8570-1s along with the Alternative CSFs and Master Labels.

Please let us know if you need additional information.

Respectfully,

Shyam K. Chari
President
Agro Logistic Systems, Inc.

Debug TURBO

PROCESSING REQUEST

Reg # 70310-6

Decision # 525622

Description: withdrawn amendment

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: C. Kendrick

Division: BPPD

Phone: 703 347 0768

Date: 2/21/17

Kendrick, Cody

From: Shyam chari <shyam@agrologistic.com>
Sent: Tuesday, February 21, 2017 12:30 PM
To: Kendrick, Cody
Cc: 'Nani Narayanan'
Subject: Amendments

Dear Mr. Kendrick:

Please disregard the amendment actions on the documents sent to you with cover letter dated January 27, 2017 for-

1. Debug Aza MUP (EPA Registration No. 70310-6)
2. Debug TGAI (EPA Registration No. 70310-4)
3. Debug Turbo (EPA Registration No. 70310-5)
4. Debug Trés (EPA Registration No. 70310-8)

I have sent a corrected version with a cover letter to you dated February 13, 2017 that supersedes the above for-

1. Debug Aza MUP (EPA Registration No. 70310-6)
2. Debug TGAI (EPA Registration No. 70310-4)

I have also sent a corrected version with a cover letter to you dated February 15, 2017 that supersedes the above for-

1. Debug Turbo (EPA Registration No. 70310-5)
2. Debug Trés (EPA Registration No. 70310-8)

Please use these corrected amendment actions instead.

Thanks.

Shyam K. Chari
Agro Logistic Systems, Inc.
Tel: 714-990-9220
Cell: 909-374-8873

S: 998219

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Company: 70310 AGRO LOGISTIC SYSTEMS, INC.

Billable: ☐ Yes ☒ No

Tracking

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-6 Product Name: DEBUG AZA MUP

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 27-Jan-2017



OPP Rec'd Date: 30-Jan-2017



Front End Date: 30-Jan-2017



Risk Manager Send Date: 31-Jan-2017



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Content

Des

CSF

Paper Label

III

View/Edit

Receipt Description:

AMENDMENT

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 31, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. SHYAM K. CHARI
AGRO LOGISTIC SYSTEMS, INC.
PO Box 5799
DIAMOND BAR, CA 91765

PRODUCT NAME: DEBUG AZA MUP
COMPANY NAME: AGRO LOGISTIC SYSTEMS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 70310-6
EPA RECEIPT DATE: 01/30/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "S. K. Chari", written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

12

Fee for Service

{998219J~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S- 998219

EPA File Symbol/Reg. No.

70310-6

Pin-Punch Date:

1/30/2017

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Byceland

Date: 1-31-17

Remarks:



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number

70310-6

2. EPA Product Manager

ANDREW BRYCELAND

3. Proposed Classification

☐ None☐ Restricted

4. Company/Product (Name)

DEBUG A2A MUP

PM#

5. Name and Address of Applicant (Include ZIP Code)

AGRO LOGISTIC SYSTEMS, INC.
P.O. BOX 5799, DIAMOND BR



Check if this is a new address

CA 91765

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)
(b)(i), my product is similar or identical in composition and labeling
to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.☐ Resubmission in response to Agency letter dated _____☐ Notification - Explain below.Final printed labels in response to
Agency letter dated _____

"Me Too" Application.



Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

CHANGE NAME & ADDRESS ON THE CSP (ALTERNATE-2)
OF THE PRODUCER (ITEM #2)

ADD NEW EPA ESTABLISHMENT NUMBER ON THE MASTER
LABEL.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____
* Certification must
be submittedIf "Yes"
Unit Packaging wgt.No. per
containerIf "Yes"
Package wgtNo. per
container

3. Location of Net Contents Information

☐ Label☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

SHYAM K. CHARI

Title

PRESIDENT

Telephone No. (Include Area Code)

714-440-9220

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or
both under applicable law.

6. Date Application
Received

(Stamped)

2. Signature

3. Title

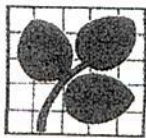
PRESIDENT

4. Typed Name

SHYAM K. CHARI

5. Date

01-27-2017



**AGRO
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.
Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

January 27, 2017

Cody Kendrick,
Regulatory Action Leader,
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs,
United States Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Reference: Debug Aza MUP- EPA Registration Number 70310-6
Debug TGAI- EPA Registration Number 70310-4
Debug Turbo- EPA Registration Number 70310-5
Debug Très- EPA Registration Number 70310-8

Dear Mr. Kendrick:

Please refer to our various email conversations and your response.

Please find attached the Non- PRIA amendments for the above products.

For all products we are attaching the Transmittal Forms, EPA Form 8570-1s along with the Alternative 2 CSFs and Master Labels.

For the EPs- Debug Turbo (EPA # 70310-5), and Debug Très (EPA# 70310-8), we are also attaching the corrected Market Labels.

Please let us know if you need additional information.

Respectfully,

Shyam K. Chari
President
Agro Logistic Systems, Inc.

Debug TURBO

PROCESSING REQUEST

Reg # 70310-6

Decision # 522605

Description: changing manufacturing process w/ new CSF, ALT. #1

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 2/15/17

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 9/20/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: C. Kendrick

Division: BPPD

Phone: 703 347 0468

Date: 2/16/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 15, 2017

Shyam K. Chari
President
Agro Logistic Systems, Inc.
P.O. Box 5799
Diamond Bar, CA 91765

Subject: Pesticide Registration Improvement Act (PRIA) Formulation Amendment – new
manufacturing process
Product Name: Debug AZA MUP
EPA Registration Number: 70310-6
Application Date: 7 October 2016
OPP Decision Number: 522605

Dear Mr. Chari:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 03/06/2015
- Alternate CSF #1 dated 09/20/2016

Any CSFs other than those listed above are superseded/no longer valid.

Page 2 of 2
EPA Reg. No. 70310-6
OPP Decision No. 522605

If you have any questions, please contact Cody Kendrick of my team by phone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Andrew C. Bryceland".

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

**OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION**

MEMORANDUM

DATE: January 26, 2017

SUBJECT: Debug AZA MUP (EPA Reg. #: 70310-6), Containing 25% of Azadirachtin as its active ingredient (a.i.). Review of Alternate CSF, Label, Product Chemistry and Toxicity Section B681 Registration

Decision Number: 502429
DP Number: 428935
EPA Reg. Number: 70310-6
Chemical Class: Biochemical
PC Code: 121701
MRIDs: 50100501 through 50100503

FROM: Manying Xue, Chemist
BPB/BPPD (7511P)

THRU: Russell Jones, Ph. D, Senior Scientist
BPB/BPPD (7511P)

TO: Cody Kendrick, Acting Senior Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

Agro Logistics System, Inc. has submitted an application for a Section B681 registration for the manufacturing use product, Debug AZA MUP (EPA Reg. #: 70310-6), containing 25% of Neem Oil as its active ingredient (A.I.) with a new manufacturing processing procedures.

In support of this registration, the registrant has submitted a label, alternate Confidential Statements of Formula (CSF), dated 09/20/16, product and data and information submission for acute toxicity studies.

BPPD has reviewed and evaluated the submissions for the registration of the manufacturing use product, Debug AZA MUP (EPA Reg. #: 70310-6). In addition, the submitted preliminary analysis from the registrant, dated, 01/26/2017 in response to the

Agency's 26 January 2017 10-day letter was reviewed. The decisions are made to reflect the current OCSPP's policies.

Conclusions:

1. The Confidential Statement of Formula (CSF), dated 09/20/2016 is **ACCEPTABLE**.

2a. Product Chemistry is **ACCEPTABLE**.

2b. The submitted preliminary analysis from the registrant, dated, 01/26/2017 in response to the Agency's 26 January 2017 10-day letter was found to be **ACCEPTABLE**.

3. The acute toxicity studies for Azadirachtin are **ACCEPTABLE** to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). Acute toxicities for the manufacturing use product, DEBUG AZA MUP should be classified as Toxicity Category IV for acute oral toxicity, acute dermal irritation, skin sensitization and for acute inhalation; Toxicity Category III acute dermal; and Toxicity Category II for acute eye irritation. The test substance is not considered to be a contact sensitizer.

4. The studies for Non-Target Organisms are not required for this registration.

STUDY SUMMARIES

Confidential Statements of Formula (CSF)

The nominal concentration and certified limit for the alternate formulation of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6) is listed in Tables 1 (see **CONFIDENTIAL APPENDIX**) for the alternate Confidential Statement of Formula (CSF), dated 09/20/16.

Physical and Chemical Characteristics

The product chemistry data for the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6) containing Azadirachtin 25% as its active ingredient is completed. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 2.

TABLE 2. Physical and Chemical Properties for DEBUG AZA MUP ^a			
Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	Light yellow powder, garlic nutty	-
830.6303	Physical State		
830.6304	Odor		
830.6315	Flammability	> 250°C (>482°F)	-
830.6317	Storage Stability	2 years	-
830.6319	Miscibility	Soluble in water. This data requirement is not applicable as the product is not intended to be mixed with petroleum solvents.	-
830.6320	Corrosion Characteristics	Not corrosive to its packaging (HDPE) containers or metals	-
830.7000	pH	3.53	-
830.7300	Density/Relative Density/Bulk Density	0.49 no unit given	-

^aData from MRID 495867-02

Product Identity and Composition

Active Ingredient:

Common name: Cold Processed Neem Oil
Chemical name: Azadirachtin
CAS: 11141-17-6
Molecular Formula: C₃₅H₄₄O₁
Molecular Weight: 720.21

Description of Starting Materials

See **CONFIDENTIAL APPENDIX**

Description of Production and Formulation

See **CONFIDENTIAL APPENDIX**

Discussion of the Formation of Impurities

See **CONFIDENTIAL APPENDIX**

Tier I Acute Toxicity (OPPTS 870.1100 - 1300 & 870.2400 – 2600)

No acute toxicity studies have submitted for the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). The registrant proposes to use acute toxicity studies for the TGAI product, Azadirachtin (EPA Reg. No.: 70310-4) to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6).

The information of acute toxicities (MRIDs: 49886703 using the TGA product, Azadirachtin (EPA Reg. No.: 70310-4) as test materials are summarized in Table 3.

TABLE 3 Acute Toxicity Profile – Azadirachtin				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	425383-02 446448-10	The oral LD ₅₀ for rats was greater than 5000 mg/kg.	IV
870.1200	Acute dermal [rat]	425383-03 446448-11	LD ₅₀ = > 2000mg/kg for rats	III
870.1300	Acute inhalation [rat]	446448-12	The single exposure acute inhalation LC ₅₀ of the test substance is greater than 0.72 mg/L in rats.	IV
870.2400	Acute eye irritation [rabbit]	425383-04 446448-13	Causes moderate eye irritation following acute exposure	II
870.2500	Acute dermal irritation [rabbit]	425383-03 446448-11 425383-05 446448-14	Slightly irritating	IV
870.2600	Skin sensitization [guinea pig]	425383-06 446448-21	The test substance is not considered to be a contact sensitizer.	IV

Conclusions:

The acute toxicity studies for Azadirachtin are **ACCEPTABLE** to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). Acute toxicities for the manufacturing use product, DEBUG AZA MUP should be classified as Toxicity Category IV for acute oral toxicity, acute dermal irritation, skin sensitization and for acute inhalation; Toxicity Category III acute dermal; and Toxicity Category II for acute eye irritation. The test substance is not considered to be a contact sensitizer.

Non-Target Organisms

The studies for Non-Target Organisms are not required for this registration.

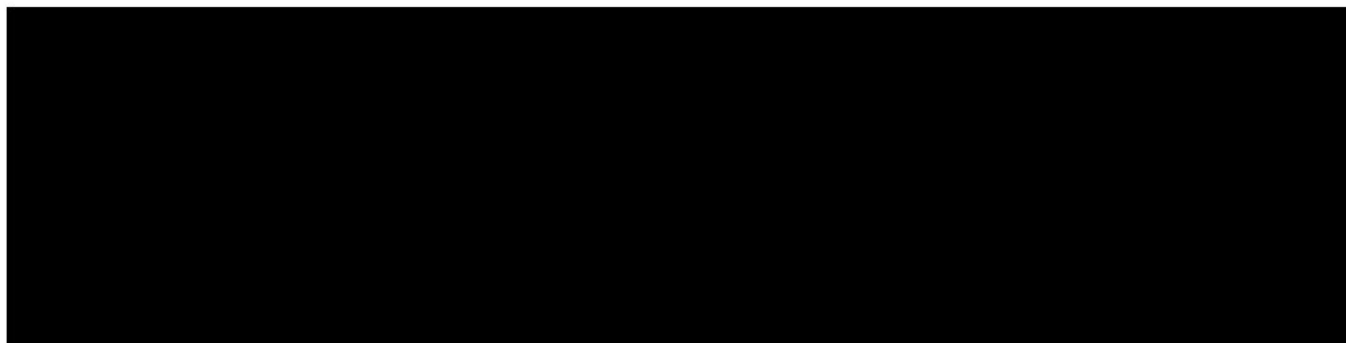
CONFIDENTIAL APPENDIX

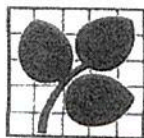
The nominal concentrations and certified limits for the alternate formulation are listed in Table 1 for the active ingredients in the manufacturing use product DEBUG AZA MUP.

TABLE 1. Nominal CSF concentrations and certified limits for Azadirachtin 25%*					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Upper	Lower
Active Ingredient					
Azadirachtin (25.0 %) (11141-17-6)	121701	Active Ingredient	25.0% (250.00)	25.75% (257.50)	24.25% (242.50)

^aData from CSF 09/20/2016

Description of Starting Materials and Description of Production and Formulation Process





**AGRO
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.
Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

January 26, 2017

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pllotion Prevention Division (7511P)
Office of Pesticide Programs
United States Environmental Protection Agency
2777 S. Crystal Drive
One Potomac Yard
Arlington, VA 22202

Reference: OPP Decision Number: 522605
EPA Registration Number: 70310-6
Product Name: Debug Aza MUP
Company Name: Agro Logistic Systems, Inc.

Dear Ms. Hollis:

Please refer to the above decision number.

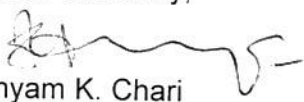
We have corrected our application to address the deficiency listed in the Confidential Appendix to your letter dated January 25, 2017.

This detail of 37 pages has already been sent as a Hard Copy to Document Processing yesterday (January 25, 2017) for delivery on January 26, 2017. An electronic copy has also been sent today to your RAL, Cody Kendrick.

This letter, in addition to sending electronically to your RAL, will be sent today as hard copy to Document Processing along with your letter for easy reference.

Thank you.

Yours Sincerely,


Shyam K. Chari



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 25, 2017

****CONTAINS CONFIDENTIAL BUSINESS INFORMATION****

BY EMAIL

RE: Deficiencies and Issues Noted During Preliminary 90 Day Technical Screen
OPP Decision Number: 522605
EPA Registration Number: 70310-6
Product Name: Debug Aza MUP
EPA Receipt Date: 7 October 2016
EPA Company Number: 70310
Company Name: Agro Logistic Systems, Inc.

Shyam K. Chari
President
Agro Logistic Systems, Inc.
PO Box 5799
Diamond Bar, CA 91765

Dear Mr. Chari:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

Specifically, you must provide the data and/or information described in the attached Confidential Appendix.

In order for the review of your pesticide product to continue, you will need to correct your application to address the item listed above within 10 business days of the date you received this letter. The EPA must receive your corrections by the 10th business day. The EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy, minus confidential information, received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

If you have questions concerning this letter, please contact Cody Kendrick of my branch by telephone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Hollis", written in a cursive style.

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: January 25, 2017

SUBJECT: Debug AZA MUP (EPA Reg. #: 70310-6), Containing 25% of Azadirachtin as its active ingredient (a.i.). Review of Alternate CSF, Label, Product Chemistry and Toxicity Section B681 Registration

Decision Number: 502429
DP Number: 428935
EPA File Symbol Number: 70310-A
Chemical Class: Biochemical
PC Code: 121701
MRIDs: 50100501 through 50100503

FROM: Manying Xue, Chemist
BPB/BPPD (7511P)

THRU: Russell Jones, Ph. D, Senior Scientist
BPB/BPPD (7511P)

TO: Cody Kendrick, Acting Senior Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

Agro Logistics System, Inc. has submitted an application for a Section B681 registration for the manufacturing use product, Debug AZA MUP (EPA Symbol #: 70310-6), containing 25% of Neem Oil as its active ingredient (A.I.) with a new manufacturing processing procedures.

In support of this registration, the registrant has submitted a label, alternate Confidential Statements of Formula (CSF), dated 09/20/16, product and data and information submission for acute toxicity studies.

BPPD has reviewed and evaluated the submissions for the registration of the manufacturing use product, Debug AZA MUP (EPA Symbol #: 70310-6). The decisions are made to reflect the current OCSPP's policies.

Conclusions:

1. The Confidential Statement of Formula (CSF), dated 09/20/2016 is **ACCEPTABLE**.
2. Product Chemistry is **UNACCEPTABLE**; the registrant needs to submit preliminary analysis (5 batches analysis) to determine the actual nominal concentration, upper and lower limits. The submission of preliminary analysis (5 batches analysis) for the alternate formulation should include the descriptions of the analytical method, validation data, method precision, accuracy, limits of detection and quantification, raw data for the 5 batches analysis (present multiple data points for each batch), result discussions, and representative chromatographs based on OCSPP Guideline 830.1700 under section (c).
3. The acute toxicity studies for Azadirachtin are **ACCEPTABLE** to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). Acute toxicities for the manufacturing use product, DEBUG AZA MUP should be classified as Toxicity Category IV for acute oral toxicity, acute dermal irritation, skin sensitization and for acute inhalation; Toxicity Category III acute dermal; and Toxicity Category II for acute eye irritation. The test substance is not considered to be a contact sensitizer.
4. The studies for Non-Target Organisms are not required for this registration.

STUDY SUMMARIES

Confidential Statements of Formula (CSF)

The nominal concentration and certified limit for the alternate formulation of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6) is listed in Tables 1 (see **CONFIDENTIAL APPENDIX**) for the alternate Confidential Statement of Formula (CSF), dated 09/20/16.

Physical and Chemical Characteristics

The product chemistry data for the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-A) containing Azadirachtin 25% as its active ingredient is completed. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 2.

TABLE 2. Physical and Chemical Properties for DEBUG AZA MUP ^a		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Light yellow powder, garlic nutty	-
830.6303 Physical State		
830.6304 Odor		
830.6315 Flammability	> 250°C (>482°F)	-
830.6317 Storage Stability	2 years	-
830.6319 Miscibility	Soluble in water. This data requirement is not applicable as the product is not intended to be mixed with petroleum solvents.	-
830.6320 Corrosion Characteristics	Not corrosive to its packaging (HDPE) containers or metals	-
830.7000 pH	3.53	-
830.7300 Density/Relative Density/Bulk Density	0.49 no units given	-

^aData from MRID 495867-02

Product Identity and Composition

Active Ingredient:

Common name: Cold Processed Neem Oil
Chemical name: Azadirachtin
CAS: 11141-17-6
Molecular Formula: C₃₅H₄₄O₁
Molecular Weight: 720.21

Description of Starting Materials

See **CONFIDENTIAL APPENDIX**

Description of Production and Formulation

See **CONFIDENTIAL APPENDIX**

Discussion of the Formation of Impurities

See **CONFIDENTIAL APPENDIX**

Tier I Acute Toxicity (OPPTS 870.1100 - 1300 & 870.2400 – 2600)

No acute toxicity studies have submitted for the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). The registrant proposes to use acute toxicity studies for the TGAI product, Azadirachtin (EPA Reg. No.: 70310-4) to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6).

The information of acute toxicities (MRIDs: 49886703 using the TGAI product, Azadirachtin (EPA Reg. No.: 70310-4) as test materials are summarized in Table 3.

TABLE 3 Acute Toxicity Profile – Azadirachtin				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	425383-02 446448-10	The oral LD ₅₀ for rats was greater than 5000 mg/kg.	IV
870.1200	Acute dermal [rat]	425383-03 446448-11	LD ₅₀ = > 2000mg/kg for rats	III
870.1300	Acute inhalation [rat]	446448-12	The single exposure acute inhalation LC ₅₀ of the test substance is greater than 0.72 mg/L in rats.	IV
870.2400	Acute eye irritation [rabbit]	425383-04 446448-13	Causes moderate eye irritation following acute exposure	II
870.2500	Acute dermal irritation [rabbit]	425383-03 446448-11 425383-05 446448-14	Slightly irritating	IV
870.2600	Skin sensitization [guinea pig]	425383-06 446448-21	The test substance is not considered to be a contact sensitizer.	IV

Conclusions:

The acute toxicity studies for Azadirachtin are **ACCEPTABLE** to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Reg. No.: 70310-6). Acute toxicities for the manufacturing use product, DEBUG AZA MUP should be classified as Toxicity Category IV for acute oral toxicity, acute dermal irritation, skin sensitization and for acute inhalation; Toxicity Category III acute dermal; and Toxicity Category II for acute eye irritation. The test substance is not considered to be a contact sensitizer.

Non-Target Organisms

The studies for Non-Target Organisms are not required for this registration.

CONFIDENTIAL APPENDIX

The nominal concentrations and certified limits for the alternate formulation are listed in Table 1 for the active ingredients in the manufacturing use product DEBUG AZA MUP.

TABLE 1. Nominal CSF concentrations and certified limits for Azadirachtin 25% ^a					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Upper	Lower
Active Ingredient					
Azadirachtin (25.0 %) (11141-17-6)	121701	Active Ingredient	25.0% (250.00)	25.75% (257.50)	24.25% (242.50)

^aData from CSF 09/20/2016

Description of Starting Materials and Description of Production and Formulation Process

Manufacturing process information may be entitled to confidential treatment
Inert ingredient information may be entitled to confidential treatment

Biochemical Pesticide Technical Screen

Date of Tech Screen Completion:01/25/2017

FAIL:

(TO BE COMPLETED BY THE RAL):

RAL and Reviewer	Cody Kendrick (RAL); Manying Xue (Science Reviewer)
File Symbol/Registration/Petition No.	70310-6
PRIA Code	B781
Submission No.	993272
Decision No.	522605

Label Review				
<i>Highlight or leave items blank if you require review by science reviewer. Use RAL Comments to provide any instructions to science reviewer.</i>				
Item:	Description:	Yes	No	N/A
a.	Label in conformance with current Label Review Manual? (Select "yes" only if all below is acceptable) Note: OK if some items are placeholders in brackets or XXX-XXX	x		
b.	Restricted Use Pesticide statement (if applicable)			X
c.	Product name, brand, or trademark	X		
d.	Ingredient statement including nominal concentration of active ingredient (AI)? Microbial: strain designation and potency designation	X		
e.	Microbial: Viability			X
f.	"Keep Out of Reach of Children" (KOOROC) Statement	X		
g.	Signal Word	X		
h.	First aid statement	x		
i.	Net contents/net weight	x		
j.	EPA Reg. No. and Establishment No.	x		
k.	Company name and address	x		
l.	Precautionary statement: Hazards to Humans and Domestic Animals Microbial: Dust Mask Statement	X		
m.	Environmental hazards	X		
n.	Physical and chemical hazards (if applicable)	X		
o.	Directions for Use	X		
p.	Worker Protection Standard (WPS) language (if applicable)			X
q.	Storage and Disposal	X		

	<ul style="list-style-type: none"> Do these instructions agree with the container types listed on Section III of 8570-1? If Section III is empty, check if the instructions agree with past master label or FPL in jacket. 			
r.	Warranty Statement	X		
s.	Batch Code	X		
RAL Comments (Summary of Deficiencies, Instructions to Science Reviewer):				

RAL Comments:

(TO BE COMPLETED BY THE REVIEWER):

Notes to reviewer: 1) when listing/discussing a specific data requirement, please also list the corresponding guideline number and 2) include the appropriate MRID number when discussing a deficiency, data, etc.

Confidential Statement of Formula (CSF)				
Item:	Description:	Yes	No	N/A
a.	Concurrence with Inerts Branch assessment of inert ingredient approval on CSF?			x
b.	CSF accurately reflects label	x		
c.	Active(s) + Inert(s) = 100%	x		
d.	Chemical names and CAS #s provided for inerts	x		
e.	Units in all applicable boxes	x		
f.	Supplier information adequately listed	x		
g.	Certified limits correct?	x		
h.	If certified limits are outside recommended range, explanation provided?			x
i.	If there are alternate formulations, are they actually alternate and not a new product?			x
Summary of deficiencies/Comments:				

Data Matrix-MP or EP				
Item:	Description:	Yes	No	N/A
a.	Are all product chemistry data requirements listed?		x	

b.	Are all mammalian toxicology data requirements listed?	x		
c.	Are all nontarget organism data requirements listed?	x		
d.	Are all efficacy data listed?			x
e.	If the a.i. is from a registered source, is the source registered for the EP's or MP's use pattern?			x

Summary of deficiencies/Comments:

I. Request the submission of preliminary analysis

Deficiency Table for EPA Reg. No./File Symbol No.:

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
List data requirement and guideline no.	List MRID No. and whether data, rationale, or waiver request were submitted.		

Tolerance/Exemption/Nonfood Determination (delete if nonfood-use or already approved for food use)	
Is this a tolerance exemption, tolerance or nonfood determination?	
Are the hazard data adequate for secondary review? If so, is there a likely endpoint?	
If there are residue, environmental fate, etc. data, do they support the petition?	

Summary of deficiencies/Comments:

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 11-1-16

Document Part Of: 70310-6
MRID, If Any: _____

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

ANDREW BRYCELAND

DATA PACKAGE BEAN SHEET

Date: 28-Dec-2016

Page 1 of 2

Decision #: 522605

DP #: (436353)

PRIA

Parent DP #:

Submission #: 993272

E-Sub #:

*** Registration Information ***

Registration: 70310-6 - DEBUG AZA MUP

Company: 70310 - AGRO LOGISTIC SYSTEMS, INC.

Risk Manager: RM 91 - Andrew Bryceland - (703) 305-6928 Room# PY1 S-8958

Risk Manager Reviewer: Cody Kendrick CKENDRIC

Sent Date:

PRIA Due Date: 01-Jun-2017

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B681) AMENDMENT, UNREGISTERED SOURCE OF ACTIVE INGREDIENT, REQUIRES DATA

Ingredients: 121701, Azadirachtin(25%)

*** Data Package Information ***

Expedited: ☐ Yes ☒ No

Date Sent: 20-Oct-2016

Due Back:

DP Ingredient: 121701, Azadirachtin

DP Title

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 17-Apr-2017

Team Name: RM 91

Science Due Date:

Reviewer Name: Xue, Manying

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

PRIA Amendment to update manufacturing process (no MRID attached right now, I emailed the registrant to send data in in the proper format)
Tech Screen Due: 1/30/17
PRIA Date: 6/1/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 21, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AGRO LOGISTIC SYSTEMS, INC.
PO.BOX : 5799
DIAMOND BAR, CA 91765

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 03-NOV-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

S: 994377

Milestone Email:

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Application Type: Amendment



Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No

Company: 70310 AGRO LOGISTIC SYSTEMS, INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91



Product #: 70310-6

Product Name: DEBUG AZA MUP

Overseer:

Me Too
Section3:

Me Too Product
Name:

Application Date: 07-Oct-2016



OPP Rec'd Date: 03-Nov-2016



Front End Date: 03-Nov-2016



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

Receipt Content

Study

CSF

View/Edit

Form A



Signature Date

Form B



Signature Date

Copy

Memorandum

70310-6

Date: 12 / 22 / 16

To: PR 91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



AGRO
LOGISTIC SYSTEMS, INC.

555 W. Lambert Road, Unit - N, Brea, CA 92821 USA

Phone: (714) 990-9220 Fax (714) 990-9222 www.agrologistic.com

29 December 2016

Cody Kendrick
Regulatory Action Leader
Biopesticides, and Pollution Prevention Division
U.S. Environmental Protection Agency
2777 South Crystal Drive
One Potomac Way
Arlington, VA 22202

Reference: Debug Aza MUP
EPA Registration Number 70310-6
Alternate Formulation

Dear Sir:

This is to state that the Debug Aza MUP – Alternate Formulation has NO label change and NO Confidential Statement of Formula change (except for A. Alternate Formulation).

The Acute Toxicity Data, and Physical and Chemical Properties will remain the same as previously submitted.

Thank you.

Yours truly,
AGRO LOGISTIC SYSTEMS, INC.

SHYAM K. CHARI

DATA PACKAGE BEAN SHEET

Date: 20-Oct-2016

Page 1 of 1

Decision #: 522605

DP #: (436353)

PRIA

Parent DP #:

Submission #: 993272

E-Sub #:

*** Registration Information ***

Registration: 70310-6 - DEBUG AZA MUP

Company: 70310 - AGRO LOGISTIC SYSTEMS, INC

Risk Manager: RM 91 - Andrew Bryceland - (703) 305-6928 Room# PY1 S-8958

Risk Manager Reviewer: Cody Kendrick CKENDRIC

Sent Date:

TENTATIVE Due Date: 01-Jun-2017

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B681) AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT; REQUIRES DATA

Ingredients: 121701, Azadirachtin(25%)

AZA

*** Data Package Information ***

Expedited: ☐ Yes ☒ No

Date Sent: 20-Oct-2016

Due Back:

DP Ingredient: 121701, Azadirachtin

DP Title:

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 17-Apr-2017

Team Name: RM 91

Science Due Date:

Reviewer Name: Jones, Russell

Andrew Bryceland

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

PRIA Amendment to update manufacturing process (no MRID attached right now, I emailed the registrant to send data in in the proper format)
Tech Screen Due: 1/30/17
PRIA Date: 6/1/17

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-11-16

Experts In-Processing Signature: B.B.

Date 10-14-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>70310-6</u>		EPA Receipt Date: <u>10-11-16</u>							
Items for Review			Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type		X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X				
	Certificate and data matrix consistent								
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				X				
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X				
5	a) Selective Method (Fee category experts use)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
	b) Cite-All (Fee category experts use)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
	c) Applicant owns all data (Fee category experts use)	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)				X				
7	Is the data package consistent with PR Notice 86-5				X				
8	Notice of Filing included with petitions				X				

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p>Comments:</p> <p>* Documentation (Perin 1/2011)</p> <p>- Required forms are complete</p> <p>* Zinco - Perin 1/2011</p> <p>- no threats to health</p> <p>* PRN 11-3 Perin 1/2011</p> <p>- no studies submitted</p> <p>DL 10-17-16</p> <p>* Overall Status: Perin 1/2011</p>				

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 14, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-522605
EPA File Symbol or Registration Number: 70310-6
Product Name: DEBUG AZA MUP
EPA Receipt Date: 11-Oct-2016
EPA Company Number: 70310
Company Name: AGRO LOGISTIC SYSTEMS, INC.

MR. SHYAM K. CHARI
AGRO LOGISTIC SYSTEMS, INC.
PO BOX 5799
DIAMOND BAR, CA 91765

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this amendment, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act. Please note that initially this amendment was miscoded as a fast-track amendment. Please disregard the letter dated October 12, 2016.

The Action has been identified as Action Code: B681

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;REQUIRES DATA SUBMISSION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-1259.

Sincerely,

A handwritten signature in black ink, appearing to be "J. L. Smith".

Front End Processing Staff
Information Technology & Resources Management Division

(83)

{993272/~

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

☐ volpay % Reduction:

S- 993272

70310-6

10/11/2016

Action Code:

Requested: BCB

Granted: B68

Amount Due: \$

Parent/Child Decisions:

Uncleared Inert in Product

Reviewer: Andrew Bryce Lewis

Date: 10/12/10

Remarks:

Assign to Cell

S: 993272

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ NoBillable: ☐ Yes ☒ No

Company: 70310 AGRO LOGISTIC SYSTEMS, INC.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-6

Product Name: DEBUG AZA MUP

Overrides:

Me Too
Section3:Me Too Product
Name:

Application Date: 07-Oct-2016



OPP Rec'd Date: 11-Oct-2016



Front End Date: 12-Oct-2016



Risk Manager Send Date: 12-Oct-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

AMENDMENT

Receipt Content

Des

CSF

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



Receipt

Your payment is complete

Pay.gov Tracking ID: 25UB04LO

Agency Tracking ID: 75106369909

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$1,520.00

Transaction Date: 10/07/2016 12:18:05 PM EDT

Payment Date: 10/07/2016

Registration Number: 70310-6

Company Name: AGRO LOGISTIC SYSTEMS INC

Company Number: 070310

Action Code: B681

Account Information

Cardholder Name: SHYAM CHARI

Card Type: Visa

Card Number: *****0217

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
shyam@agrologistic.com

DP#: (436353)

*** Studies Sent for Review ***

Decision#: (522605)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50100501		Chari, S. (2016) Description of Starting Materials. Project Number: 70310/6/1. Unpublished study prepared by Agro Logistic Systems, Inc. 4p.	880.1200/Description of starting materials, production and formulation process	
50100502		Chari, S. (2016) Discussion of Formation of Impurities. Project Number: 70310/6/2. Unpublished study prepared by Agro Logistic Systems, Inc. 4p.	880.1400/Discussion of formation of impurities	
50100503		Chari, S. (2016) Preliminary Analysis. Project Number: 70310/6/3. Unpublished study prepared by Agro Logistic Systems, Inc. 4p.	830.1700/Preliminary analysis	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70310-6	2. EPA Product Manager ANDY BRYCE LAND	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DEBUG AZA MUP	PM#	
5. Name and Address of Applicant (Include ZIP Code) AGRO LOGISTIC SYSTEMS, INC. P.O. BOX: 5799, DIAMOND BAR, CA 91765 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA - B 651 - ATTACHED - PRIA-PAYMENT RECEIPT, SMALL BUSINESS CERTIFICATION FORM, OC SPP \$80.1200, OC SSP \$80.1400, OC SSP \$80.1700, CSP (Alternate Formulation), Flow chart (Alternate Formulation). NO change in LABEL.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name SHYAM K. CHARI	Title PRESIDENT	Telephone No. (Include Area Code) 714-990-9220
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title PRESIDENT	
4. Typed Name SHYAM K. CHARI	5. Date 10-07-2016	

PROCESSING REQUEST

Reg # 70310-6

Decision # 521827

Description: adding alternate formulation with new
manufacturing process

Electronic Label & Letter (see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 11 OCT. 2016

☐ Dated:

*** Only one label type should be selected ***

Other Materials Sent (see jacket):

☐ New CSI²(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: C. Kendrick

Division: BPPD

Phone: 703 347 0468

Date: 11 OCT. 2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 11, 2016

Shyam K. Chari
President
Agro Logistics Systems, Inc.
PO Box 5799
Diamond Bar, CA 91765

Subject: Formulation Notification per Pesticide Registration Notice (PRN) 98-10 – adding alternate formulation with new manufacturing process
Product Name: Debug Aza MUP
EPA Registration Number: 70310-6
Application Date: 20 Sep 2016
OPP Decision Number: 521827

Dear Mr. Chari:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action does not clearly fall within the scope of PRN 98-10 and will require additional review of the related records. A summary of our findings include the following:

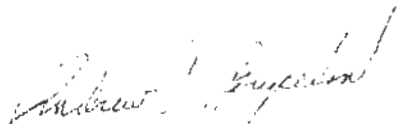
- I. As a submission to update the manufacturing process of the product, data would need to be reviewed to address the following data requirements:
 - a. Description of starting materials, production and formulation process (OCSPP 880.1200).
 - b. Discussion of formulation of impurities (OCSPP 880.1400), and
 - c. Preliminary analysis (OCSPP 830.1700).

Please be advised that Pesticide Registration Notices are provided as guidance; they are not considered regulation by the EPA. Therefore, BPPD reserves the right to make the above determination, and no further processing of this application will occur. You may submit, as a Pesticide Registration Improvement Act amendment, a new application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that the change proposed is not permitted by notification.

Page 2 of 2
EPA Reg. No. 70310-6
OPP Decision No. 521827

If you have any questions, you may contact Cody Kendrick of my team by phone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Bryceland".

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

S 992439

Milestone Email

Regulatory Type: Product Registration - Section 3

Application Type: Notification

Company: 70310 AGRO LOGISTIC SYSTEMS INC

Fee For Service: Yes ☐ No ☐

Print Letter

Enter More Information

Tracking

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-6

Product Name: DEBUG AZA MUP

Me Too
Section3Me Too Product
Name:

Application Date: 20-Sep-2016



OPP Rec'd Date: 22-Sep-2016



Front End Date: 22-Sep-2016



Risk Manager Send Date: 22-Sep-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Des

CSF

View/Edit

Receipt Description

Notification - Alternate Formulation CSF Alternate



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70310-6	2. EPA Product Manager ANDREW BRYCE LAND	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DEBUG AZA MUP	PMF	
5. Name and Address of Applicant (Include ZIP Code) AGRO LOGISTIC SYSTEMS INC PO BOX 5799, DIAMOND BAR, CA 91765		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

ALTERNATE FORMULATION - FLOW CHART & MANUFACTURING PROCESS IS ATTACHED. ALTERNATE CSF IS ATTACHED.
NO CHANGE IN CSF (CONFIDENTIAL STATEMENT OF FORMULA)
NO CHANGE IN LABEL

Section - III

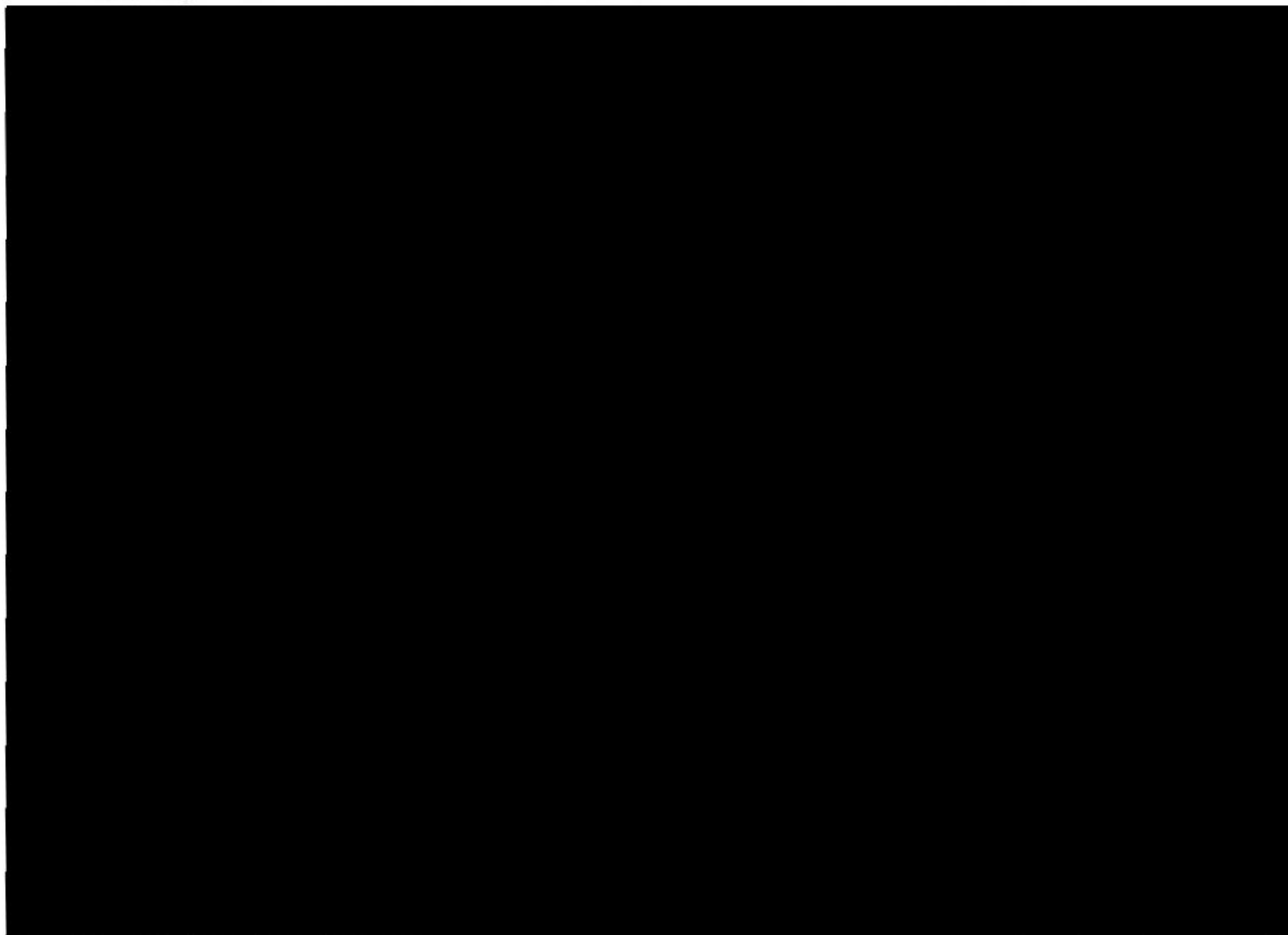
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name SHYAM CHARI	Title PRESIDENT	Telephone No. (Include Area Code) 714-990-9220	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title PRESIDENT		
4. Typed Name SHYAM CHARI	5. Date 09-20-2016		

Alternate Formulation for DEBUG AZA MUP (EPA Registration Number 70310-6)

Description Of Starting Materials, Production And Formulation Process (OPPTS 880.1200).



PROCESSING REQUEST

Reg # 70310-6 Decision # 502429

Description: New Product Registration

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 1/13/2016

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 8/19/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Gina Burnett

Division: BPPD

Phone: 703-605-0513

Date: 2/24/2016



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

70310-6

Date of Issuance:

1/13/2016

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

DEBUG AZA MUP

Name and Address of Registrant (include ZIP Code):

Agro Logistic Systems, Inc.
P.O. Box 5799
Diamond Bar, CA 91765, U.S.A.

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.

Signature of Approving Official:

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

Date:

1/13/2016

2. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 70310-6."
3. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 08/19/15

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Gina Burnett of my team by phone at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,



Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Manufacturing process information may be entitled to confidential treatment